

The Value of Information Technology-Enabled Diabetes Management

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Improving Healthcare Value

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Published and distributed by the Healthcare Information and Management System Society (HIMSS).

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ISBN: 0-9777903-5-5

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Chapter 1. Introduction.....	1
Background.....	1
Value Proposition and Research Gaps	3
Chapter 2. Approach to the Analysis.....	7
Introduction	7
Available Technologies: ITDM Taxonomy.....	8
How Technologies Affect Processes of Care: ITDM Impacts Engine.....	10
How Changes in Processes of Care Result in Improved Clinical and Economic Outcomes: ITDM	
Disease-Burden Engine.....	11
Costs of the Systems: ITDM Implementation-Cost Engine	13
How Patient Participation Affects Value: ITDM Population-Selection Engine.....	16
How Costs and Benefits Apply to Different Settings: ITDM Net-Benefit Projection Engine	17
Sensitivity Analysis and Stability Testing	19
Approach-to-Analysis Summary	19
Chapter 3. Results	23
Common Assumptions.....	23
Technologies Used by Payers	23
Technologies Used by Providers	25
Technologies Used by Patients	27
Integrated Provider-Patient Systems.....	29
Net Benefit to Organizations.....	31
Sensitivity Analysis and Stability Testing	31
Additional Benefits	31
Chapter 4. Discussion.....	33
Key Limitations	34
Conclusion	36
Acknowledgments.....	39
Appendix 1: Literature Summary	41
Appendix 2: Intervention-Cost-Engine Estimates.....	43
Appendix 3: Expert-Panel Biographies.....	47
References	53
Index.....	57



Background

Diabetes, a condition in which the body has lost the ability to produce, or to correctly utilize insulin, is the fifth-leading cause of death by disease in the United States.¹ An estimated 20.8 million Americans have diabetes,² and the American Diabetes Association (ADA) reports that in 2002 the direct and indirect costs of the disorder totaled more than \$132 billion.³

Because of demographic shifts—changes in population size, age distribution, and ethnic diversity, for example—the ADA projects that by 2010 the number of patients with diabetes will have risen by 20 percent and associated costs will be \$156 billion.³ Even more alarming is the fact that these estimates may actually be conservative, given that more Americans than ever are struggling with diabetic risk factors such as obesity.

The outlook for patients with diabetes is improving, however, as better knowledge of diabetes provides them a broader array of options. Landmark studies have shown that tight management of the disease can prevent many complications, including stroke, blindness, heart disease, and death. Further, treatments such as laser eye surgery can help control complications after they develop. In addition, an improved understanding of risk factors for diabetes has enabled earlier diagnosis, even prevention.⁴

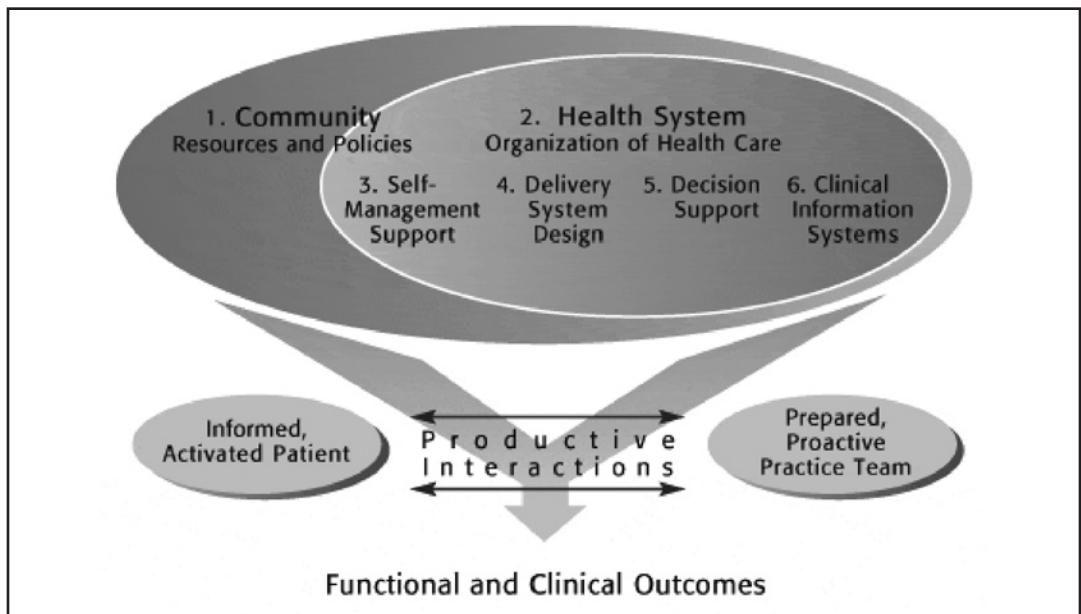
Although these advances have resulted in widely cited guidelines to providers, patients with diabetes often fail to receive the recommended care; a survey conducted by McGlynn in 2004 revealed that physicians complied with diabetic guidelines less than half the time.⁵ This noncompliance results in part from the structure of our health care system, which—despite recognition that chronic conditions such as diabetes account for the majority of health care costs—is oriented toward treating acute problems.⁶ Chronic conditions require ongoing multidisciplinary care, as opposed to infrequent visits to a physician's office, and they require patient education on self-care—blood-sugar monitoring, adherence to dietary recommendations, exercise, and regular foot inspection, for example.

The “chronic care model” and “disease management” are approaches designed to meet many of these needs.⁷ The chronic care model integrates community resources, health system organizations, and self-management with the aid of mechanisms such as decision-support and clinical-information systems (Figure 1-1).^{8,9} It provides multidisciplinary

evidence-based care and gives the patient the education and tools needed for intimate involvement in the management of his or her disease.

Figure
1-1

Chronic Care Model⁸



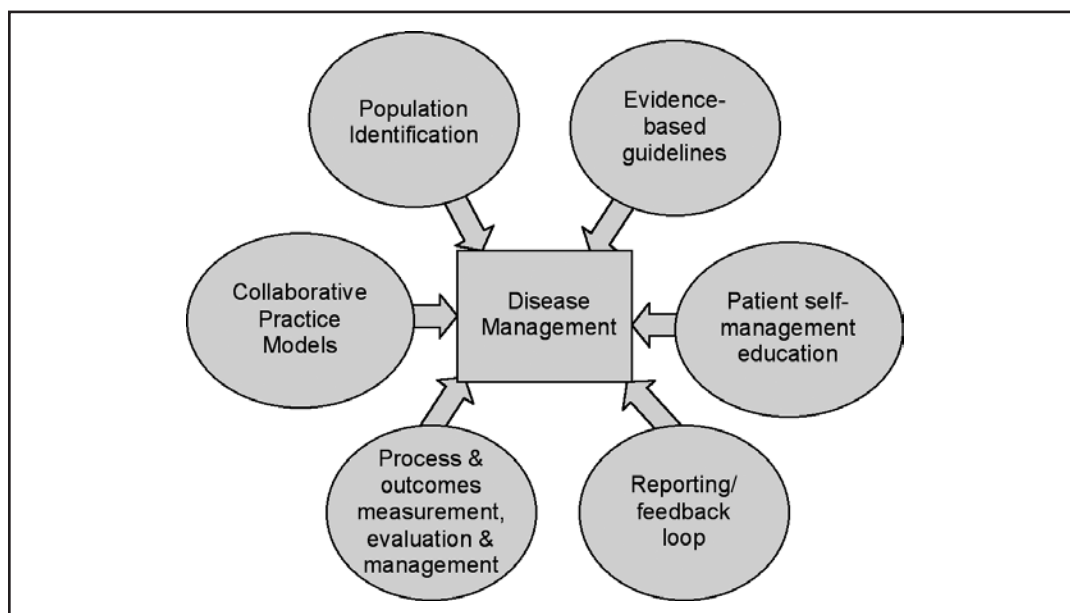
Disease management is defined as “a system of coordinated health care interventions and communications for populations with conditions in which patient self-care efforts are significant.”¹⁰ It is rooted in the assumption that care for chronic diseases can be greatly improved without the organizational changes required by the chronic care model.⁷ Most disease management programs are built around four specific processes concerning patients—identification, enrollment, engagement, and retention—which work in concert to improve quality of care and outcomes (Figure 1-2). In fact, payers, recognizing that disease management may help avoid or delay costly complications of chronic diseases, have been investing in disease-management programs, many of which only indirectly involve physician practices.¹¹ Such programs emphasize the empowerment of patients to manage their own care and to use evidence-based guidelines to help them stay as healthy as possible.¹⁰

A growing body of literature suggests that diabetes-management programs in particular need an information technology (IT) backbone in order to be effective. For instance, the Health Care Delivery Work Group from the National Institutes of Health’s Behavioral Research and Diabetes Conference concluded in 1999 that in order for a diabetes-management program to be successful “it is necessary to have a clinical information system” to support it.¹² The advantages of IT tools include: promoting better

provider-guideline compliance by presenting recommendations at the point of care; helping to identify patients overdue for care and assisting providers to proactively reach out to them; enabling patients to manage their own care through education and communication tools that allow them to receive direct feedback; and providing numerous other benefits as well.

Components of Disease Management

Figure
1-2



Value Proposition and Research Gaps

IT-enabled diabetes management is believed to create value by improving processes of care, which reduces the rate of diabetic complications, which in turn produces both cost savings and enhanced quality of life. But the literature on cost-benefit and cost-effectiveness measures of diabetes management has been limited. Shortcomings in the literature include brief study durations, a lack of generalizability of results to external settings and populations, and failure to account for factors such as identification, enrollment, and retention of patients. In a 2004 analysis of the general disease-management literature, the Congressional Budget Office reported that there is “insufficient evidence to conclude that disease-management programs can generally reduce overall health spending.”¹³

Examples of questions unanswered by the current literature include:

Do short-term improvements result in long-term benefit? By necessity, studies reported in the existing literature usually focus on narrow and specific outcomes over

short periods of time. The time and money required to conduct a long-term population study are not available for most organizations implementing diabetes management. When short-term improvements are seen in these studies, they may not be indicators of long-term benefit, merely delaying diabetic complications rather than preventing them.

How do study results generalize to other settings? The effectiveness of diabetes-management programs depends in large part on the characteristics of its patients. A relatively healthy patient population will suffer fewer complications than a population at higher risk and will have less opportunity for improvements in outcomes. Therefore results from a study conducted on young patients with diabetes may not apply, for example, to an older and less healthy Medicare population.

What are the total costs of the programs? Many studies fail to provide any cost data. Others report some costs but fail to include measures such as the cost of the intervention itself or of identifying eligible patients. Without a full accounting of all the costs of diabetes management, cost-benefit analyses will paint an overly rosy picture.

Are all eligible patients identified and enrolled in the program? Studies conducted in controlled environments may fail to account for problems associated with the identification and enrollment of patients with diabetes in real-world situations. Failure to efficiently identify and enroll all eligible patients—typically, because of tight constraints on time and money—may result in some patients not receiving the benefit of management. Such omissions reduce the economic benefits that the program might have realized.

What happens to benefits when the patient changes programs? Because diabetic complications are slow to develop, continuity of care is critical to the success of disease management; it may take years of tight control for a patient with diabetes to avoid complications such as a heart attack or blindness. When patients choose or are forced to change health plans or providers, and are obliged to leave a diabetes-management program prematurely, they may not have had time to change the course of their disease and reap the benefits of management.

Does an IT-enabled diabetes management program make sense for smaller provider organizations? Because small-group practices deliver a substantial fraction of chronic care, disease management in those venues can substantially improve the health of patients with diabetes. However, because small practices may not be able to realize the benefits of economies of scale, their costs of implementing diabetes-management programs may be prohibitive. A thorough understanding of the cost considerations of alternate approaches to IT-enabled diabetes management will allow practices of all sizes to make informed decisions regarding the net value of such programs.

Does it make sense for payers? IT-enabled diabetes management may provide payers with substantial savings from avoided health-care-utilization costs. However, premature health-plan switching by patients may prevent payers from realizing these savings. Further, payers are limited in their management options. Unlike providers, they cannot prescribe medications directly; they can only encourage providers and empower patients to make the best decisions.

What are the technology options? In choosing an IT-enabled diabetes-management program to implement, today stakeholders are faced with a multitude of options. Confusion results from the lack of comparative-benefit studies, without which an intelligent choice is reduced to mere guesswork.

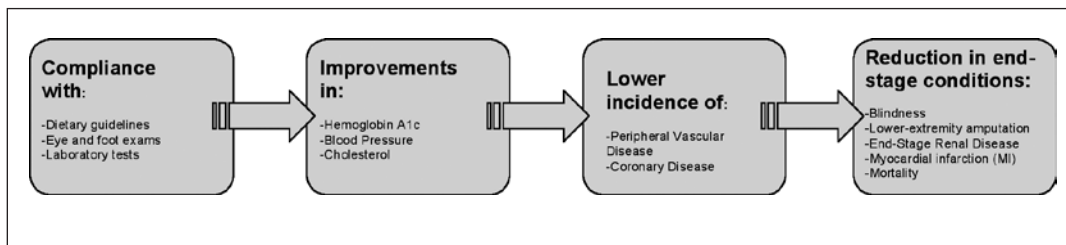
In this report, the Center for Information Technology Leadership (CITL) has addressed these and other outstanding questions with regard to IT-enabled diabetes management.

Introduction

IT-enabled diabetes management (ITDM) helps to improve diabetic-care processes, which in turn reduces the rate of diabetic complications, thereby generating clinical and economic benefit (Figure 2-1). For instance, ITDM promotes strict dietary compliance, which improves blood-sugar levels and lessens damage to small blood vessels throughout the body. This reduction in microvascular disease lowers rates of diabetes complications such as blindness, lower-extremity amputations, and end-stage renal disease. Such outcomes not only improve patients' quality of life but also reduce utilization of health care resources, potentially leading to cost savings. We have thus focused our analysis on savings that result from improved care and reductions in complications, specifically for patients with Type 2 diabetes.

Improvements Lead to a Reduction in Complications (adapted from CBO Report ¹³)

Figure
2-1



CITL convened a highly qualified expert panel of nationally recognized experts who were interviewed by phone using a structured set of questions, participated in a one-day roundtable discussion, and were consulted throughout the project. The members of that panel included:

- Madhu Agarwal, MD, Acting Deputy Chief Officer of Patient Care Services, Veterans Administration
- Brian Austin, Deputy Director, The Improving Chronic Illness Care Program, Group Health Cooperative, Seattle
- Stephen J. Brown, President and CEO, Health Hero Network, Redwood City, Calif.
- Lawrence P. Casalino, MD, PhD, Assistant Professor, University of Chicago

- Timothy G. Ferris, MD, MPH, Partners/MGH Institute for Health Policy, Massachusetts General Hospital, Boston
- Jeremy Grimshaw, MBChB, Director, Centre for Best Practices, Institute of Population Health, University of Ottawa
- Karen M. Kuntz, ScD, Associate Professor, Harvard School of Public Health, Boston
- John A. Merenich, MD, Regional Director, Chronic Disease Management Program, Colorado Permanente Medical Group, Denver
- David Wennberg, MD, President and COO, Health Dialog Analytic Solutions, Boston

This chapter describes how CITL approached fundamental questions in order to model the value of ITDM, estimate costs associated with implementing it, and understand how efficiencies influence realization of net benefit. The chapter provides detail on the taxonomy that CITL developed for these diabetes-management strategies, the approach used to construct the value model, the methodology for determining model inputs, and the way in which we determined which process outcomes were to be evaluated. To these ends, the sections in this chapter address the following questions:

- What ITDM technologies are available?
- How do ITDM technologies affect processes of care?
- How do ITDM-influenced changes in processes of care result in improved clinical and economic outcomes?
- What are the costs of ITDM systems?
- How does patient participation affect the value of ITDM?
- How do these costs and benefits apply to ITDM in a particular setting?
- How stable are the ITDM cost and benefit projections?

Available Technologies: ITDM Taxonomy

To help frame subsequent analysis, CITL derived the following taxonomy of ITDM technologies, which is described in detail below:

- Technologies used by payers
- Technologies used by providers
 - Disease registries
 - Clinical decision-support systems
- Technologies used by patients
 - Self-management
 - Remote monitoring
- Integrated provider-patient systems

Technologies Used by Payers

Payer systems interface with electronic-claims systems to track patients with diabetes and monitor diabetic-specific information. Payer systems compare patient data with

recommended guidelines in order to identify opportunities for improved management; provide feedback to patients and providers by telephone, email, or postal mail; and can focus on behavioral change, using health coaches to convey educational and motivational information to patients. The systems, which may be based at the payer organizations themselves or at separate disease-management companies, involve only those two entities and patients. There is typically no point-of-care component, though many programs do follow up with providers during or after an intervention.

Technologies Used by Providers

Diabetes registries track patients with diabetes and store information specific to their care. At the point of care, registries may generate concise patient reports for clinicians that highlight areas for attention during the office visit. Registries may also aggregate information across the population to generate “report cards,” which show, for example, the proportion of patients with diabetes who had foot exams during the prior six months or a list of patients with hemoglobin A1c (HbA1c) levels above 7 percent, which indicates that the patient’s blood-sugar level is too high. Registries may also use these report cards to facilitate a provider’s communication with patients—for instance, to generate lists for announcements about available diabetes-education sessions or to facilitate appointment scheduling.

Clinical decision-support systems (CDSSs) generate alerts and reminders for clinicians during a patient visit. Such communications may caution providers about potential errors or remind them of recommended guidelines for improving quality of care. In addition, CDSSs may offer information that helps providers navigate the complex array of treatment options by suggesting regimens based upon a patient’s condition. Unlike diabetes registries, CDSSs are built on electronic medical records (EMRs), which maintain comprehensive health data about each patient. Though EMRs are not generally designed for population-level reporting, providers and their office staff may query them to generate such information.

Technologies Used by Patients

Self-management technologies provide patients with educational resources and data-gathering mechanisms for managing their own care between provider visits. These technologies include automated phone systems that generate reminders or offer educational content; electronic diary tools that collect information to be taken to a visit; interactive educational programs on computers; and online resources, such as peer support groups, sponsored by providers.

Remote-monitoring technologies capture and send providers information that is needed to facilitate diabetes management between office visits; patients periodically submit structured electronic data about their condition—via a telephone’s touchtone keypad, for example—and they receive feedback and instructions. Newer remote-monitoring programs use Web sites that accept data uploaded directly from glucometers and other

home devices. Although the focus of remote-monitoring technologies is on the data sent from the patients' homes to providers' offices, some systems also deliver educational content to patients, content such as self-care advice in recorded phone messages, when they submit their data. These systems may also connect patients to resources such as EMRs, endorsed educational materials, interactive self-care tools, and provider e-mail.

Integrated Provider-Patient Systems

CITL envisions a fully integrated chronic-care platform that would coordinate the delivery of evidence-based care across multiple care settings, including outpatient clinics and patients' homes. This system would include a disease registry to manage chronically ill populations, patient education tools to support self-management, and remote-monitoring devices to measure and report patient symptoms and clinical progress to providers between visits. Although we could not find an example of such an integrated system, we included it in our analysis to show its potential impact.

How Technologies Affect Processes of Care: ITDM Impacts Engine

CITL surveyed the literature to find the best estimates for the impacts that each form of ITDM has on Type 2 diabetes care processes. We then created the ITDM Impacts Engine to transform *reported* evidence of physiologic and care-process improvements into *expected* process improvements for new care settings over time.

Data Sources

CITL relied on a variety of sources to estimate the impact of each diabetes-management strategy on care processes. We searched academic publications and a wide array of non-academic literature, including trade journals, government publications, the general press, vendor and consultant studies, proprietary research services, and studies by foundations and professional associations. Preference was given to evidence published in peer-reviewed literature.

For each data element in the model, we chose from the evidence a single best estimate, based on study design strength and closeness of fit to the taxonomy. We applied a standardized quality-scoring sheet to each study without regard to the direction or magnitude of its result.

We used data from these studies as inputs into the ITDM Impacts Engine. In certain instances, CITL was required to convert some of these data into a format usable by the model. Table 2-1 details the final ITDM impact data used in the ITDM Impacts Engine; Appendix 1 summarizes the studies from which these inputs were derived.

Physiologic and Care-Process Improvement Evidence from Literature Review and Evidence Synthesis

Table
2-1

		Blood Glucose	Blood Pressure	Cholesterol	Eye Exam Screening	Foot Exam Screening	Microalbumin Screening
Payer	Payer	<i>HbA1c (%)</i> 8.36 to 8.02 ¹⁴	<i>SBP (mmHg)</i> 132.5 to 128.7 ¹⁵	<i>LDL (mg/dl)</i> 114 to 104.6 ¹⁵	<i>Rate (%)</i> 40 to 48 ¹⁶	<i>Rate (%)</i> 2 to 25 ¹⁷	<i>Rate (%)</i> 27.3 to 37.3 ¹⁶
Provider	Clinical Decision Support Systems	<i>HbA1c (%)</i> 8.4 to 8.17 ¹⁸	<i>SBP (mmHg)</i> 138.1 to 139 ¹⁸	<i>LDL (mg/dl)</i> 126.7 to 112 ¹⁸	<i>Rate (%)</i> 12.2 to 19.3 ¹⁹	<i>Rate (%)</i> 46.2 to 55.6 ¹⁹	<i>Rate (%)</i> 23.3 to 43.6 ¹⁹
	Diabetes Registries	<i>HbA1c (%)</i> 7.3 to 6.1 ²⁰	<i>SBP (mmHg)</i> 140 to 139.1 ²⁰	<i>LDL (mmol/dl)</i> 3.2 to 2.7 ²⁰	<i>Rate (%)</i> 36 to 69 ²⁰	<i>Rate (%)</i> 67 to 88 ²⁰	<i>Rate (%)</i> 27 to 55 ²⁰
Patient	Remote Monitoring	<i>HbA1c (%)</i> 9.5 to 8.6 ²¹	<i>SBP (mmHg)</i> 141 to 131 ²¹	<i>LDL (mg/dl)</i> 100 to 94 ²¹			
	Self-management	<i>HbA1c (%)</i> 7.45 to 7.42 ²²		<i>Total Chol:HDL</i> 5.7 to 5.13 ²²			

HbA1c = hemoglobin A1c, SBP = systolic blood pressure, LDL = low-density lipoprotein, HDL = high-density lipoprotein

Model Development

Six care-impact measures were chosen for inclusion in the Impacts Engine, based on whether they (1) were consistent with diabetes-care guidelines,⁴ (2) could be incorporated into the CITL Diabetes Disease-Burden Engine, described below, and (3) could be reported across all technologies in the taxonomy. These criteria ensured that the resulting impacts would be consistent with scientific knowledge, project both clinical and economic benefit in our model, and produce results that were comparable across all forms of ITDM in our taxonomy. The resulting measures were changes in HbA1c, systolic blood pressure (SBP), and cholesterol levels, as well as the rates of eye exams, foot exams, and microalbuminuria screening.

Some outcomes of diabetic-care guidelines, such as pneumococcal vaccinations rates, were not included because their clinical impact could not be incorporated into the model. Other outcomes, such as emergency-department visits and avoided admissions, were not modeled because the impact of ITDM on them was inconsistently reported. Also, although we built into our model the ability to incorporate foot-ulcer and amputation rates, we did not find evidence in the literature that ITDM affected these outcomes.

How Changes in Processes of Care Result in Improved Clinical and Economic Outcomes: ITDM Disease-Burden Engine

The next step in assessing ITDM value was the projection of care-process improvements on clinical outcomes and complications from Type 2 diabetes. To this end, we created the Disease-Burden Engine.

Data Sources

Because many disease-state models have been developed to project the future disease burden of diabetes and its complications, we surveyed these models to find one that we could reuse and extend. The model had to account for the social, economic, and health care environments of the United States. It had to be modifiable, so that it could incorporate the effects of ITDM interventions. Finally, it had to be flexible enough to handle additional model parameters to address hypotheses of interest.

We chose as a starting point for our Disease-Burden Engine a model created by the Centers for Disease Control and Prevention (CDC) in conjunction with the Research Triangle Institute (RTI).^{23,24} This model was developed for the health care environment in the United States and allowed modifications for measuring the full spectrum of IT's potential alterations of the course of disease. However, the model was based only on newly diagnosed diabetics and did not account for the impact of changes in preventive screening rates and other process-of-care improvements. Therefore we extended the CDC/RTI Diabetes Cost-Effectiveness model to include such effects, and we combined it with another published model to account for the impact of diabetic retinopathy screening.²⁵ We also expanded the model to simulate patients with pre-existing diabetes and other demographic variations in the patient population.

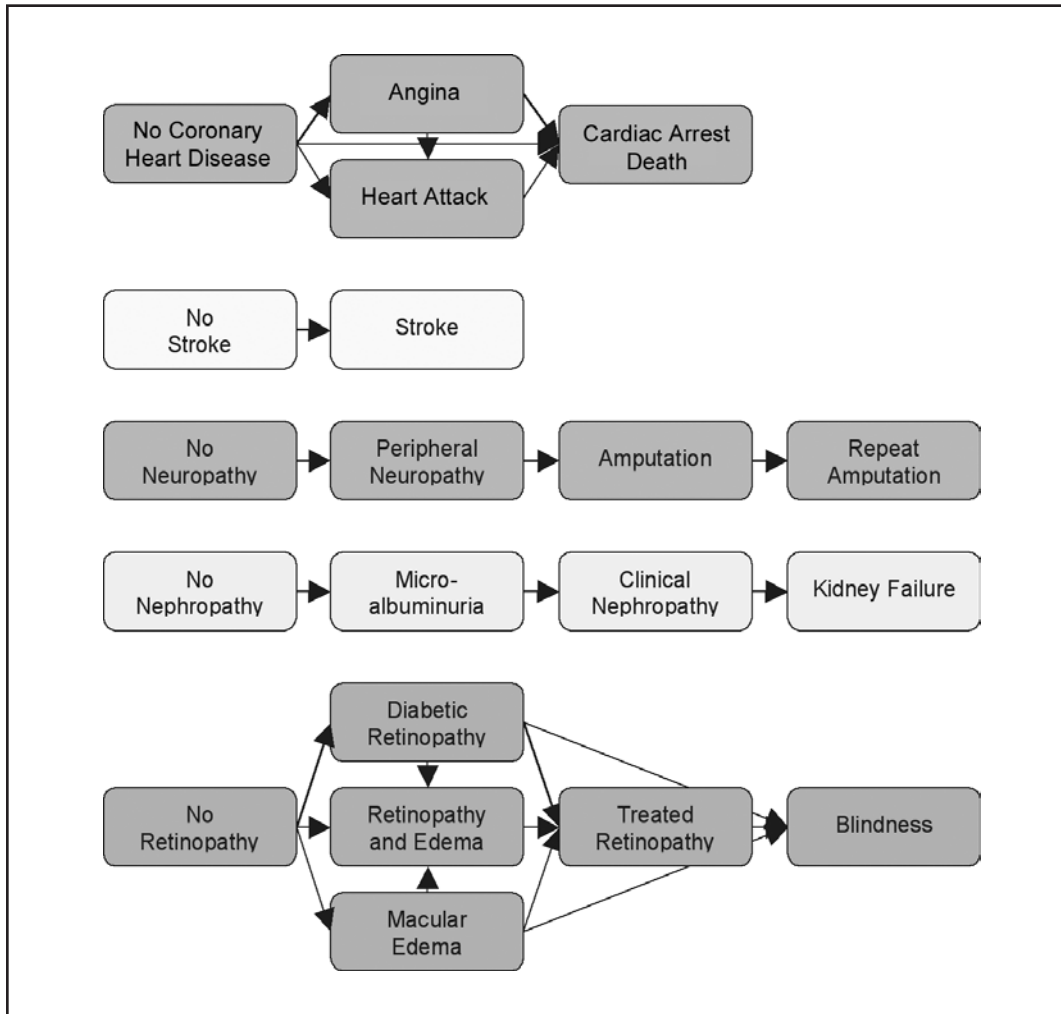
Model Development

The resulting Disease-Burden Engine characterizes five complications of diabetes: nephropathy, peripheral neuropathy, retinopathy, coronary heart disease (CHD), and stroke (Figure 2-2). The Engine specifies various levels of severity for each complication and how patients with diabetes may progress through those disease states. For example, in the case of CHD, a patient may progress from normal to angina, suffer a heart attack, and ultimately die.

Combined with the ITDM Impacts Engine, the Disease-Burden Engine predicts the degree to which care-process improvements decrease the chance that a patient will progress to a more severe disease state. Estimates of such changes were derived from the medical literature, consistent with the original CDC model. Where credible medical evidence was lacking, no benefit was projected. For example, while the landmark United Kingdom Prospective Diabetes Study reported that improved glucose control might lower the risk of heart attacks,²⁶ this result just missed statistical significance and was therefore not included in the model.

Simplified Schematic of Model Disease States

Figure
2-2



Costs of the Systems: ITDM Implementation-Cost Engine

CITL created the Implementation-Cost Engine to estimate the expenses involved in implementing and operating each form of ITDM.

Data Sources

Because published cost estimates are not widely available, CITL relied primarily on market research for these data. With the help of the Disease Management Association of America (DMAA), CITL collected information via structured phone interviews with 38 organizations currently implementing ITDM or that sell diabetes-management technologies. CITL interviewed at least one and up to sixteen confidential sources for each form of ITDM represented in our taxonomy.

Model Development

With the exception of Payer ITDM (in which diabetes management is generally outsourced), the Implementation-Cost Model was built from the following common components:

- *Identification*. Costs incurred for identifying all eligible patients with diabetes from the entire pool of patients.
- *Hardware*. Costs incurred for obtaining hardware (e.g., computers) necessary to support the IT diabetes-management program.
- *Software*. Software-licensing costs, when software must be purchased. Programmer costs, when applications must be developed.
- *Interfaces*. Costs to transform data from external systems into a standard format for the diabetes-management application.
- *IT support staff*. Staff costs required specifically for IT components of the management program.
- *Training*. Costs to train users of the systems.
- *Non-IT programmatic costs*. Costs incurred to implement diabetes-management programs that are unrelated to their IT components.

Technologies Used by Payers

For payer technologies, we assumed that the payers identify eligible patients in their plans and then hand over diabetes management to an external disease management vendor. Thus the Implementation-Cost Engine applies costs to the payers in setting up and running claims analyses that identify patients with diabetes, and it applies the costs of staff to support the program as well. The Engine then applies program-management costs including an implementation fee and a per-intervened-patient-per-month (PIPM) cost, wherein many of the cost components are bundled together. This PIPM fee varies by size of the intervened population and their insurance status.

Technologies Used by Providers

For diabetes registries, the Implementation-Cost Engine assumes that practices purchase a registry application from a vendor and run it as an application service provider (ASP) model, thus minimizing the requirements for on-site development and support. The main cost driver of this approach is the expense of building interfaces to existing practice systems. We assumed that providers would require three such interfaces, based in part on reports in the literature.²⁷ Additional expenses include the costs of personal computers (PCs) for providers to run the application at the point of care, annual license fees for software and hosting services, costs of setting up and running claims analysis to identify patients with diabetes, and costs of quarterly alerts and reminder mailings to patients.

For clinical decision support, the Implementation-Cost Engine focuses on costs associated with modifying existing EMRs in order to sustain robust diabetes management. The main expense, applied as a fixed cost to the organization, is in the time required to

develop and implement diabetes guidelines in the EMR. We did not include the costs of implementing the original EMRs themselves. Other expenses include the cost of a part-time program manager to oversee the effort.

Technologies Used by Patients

For remote monitoring technologies, the Implementation-Cost Engine assumes that each patient with diabetes is given a device that connects a glucometer to a telephone line and uploads data. Major cost drivers in this approach are data-transmission devices and software-licensing fees for each patient, as well as personal computers, software-licensing fees, and staff time for registered nurses who monitor and respond to incoming data. Additionally, there are the costs to set up and run claims analysis to identify patients with diabetes, interface costs for ensuring that practice systems will accept incoming data, and training costs for staff and patients.

For self-management technologies, the Implementation-Cost Engine assumes that patients are given access to a Website with education modules and customized self-management tools. The main cost drivers of this approach are PCs for clinical staff (dietitians, diabetes educators), staff time dedicated to providing tailored feedback and to moderating group forums, and the annual per-patient and per-dietician software fees charged by the vendor. Additional costs are those incurred in setting up and running claims analysis to identify diabetics, building an interface to the practice system, and training staff and patients.

Integrated Provider-Patient Systems

For integrated diabetes-management systems, the Implementation-Cost Engine assumes that diabetes registries are extended with remote-monitoring and self-management technologies to allow a more comprehensive diabetes-management approach—one that fully involves both providers and patients. The cost of this approach is the sum of the costs for the diabetes-registry-application, remote-monitoring, and self-management platforms. Any double-counted costs, such as identification and interface costs, were removed.

Key Assumptions: Cost Estimates for Components

Several assumptions applied throughout the cost modeling:

- Phone and Internet connectivity exist where needed, and these costs are not included in the model.
- Hardware is replaced every five years.
- Annual software maintenance represents 20 percent of acquisition cost.
- Annual interface maintenance represents 17.5 percent of acquisition cost.
- Organizations begin ITDM activity with no diabetes-specific IT or disease-management intervention already in place.
- Economies of scale and volume discounts are taken into account, where possible.

Costs were normalized to 2004 dollars, using Consumer Price Index data.²⁸ Staff costs were calculated as annual fully loaded salaries (base pay plus fringe benefits) and then broken down into hourly costs for a 40-hour workweek. Cost estimates for the approaches were not intended to account for all of the costs associated with any particular intervention approach; they were solely meant to capture an average cost associated with using a particular type of IT. Therefore CITL excluded several costs from the model. These included the costs of (1) conversion of legacy data or data cleaning, (2) sales or pre-sales activities such as contracting, (3) patient-support technologies such as basic glucometers, (4) patient or provider recruitment or marketing, (5) program planning and development, (6) increases or decreases in time for providers and their staff to use the IT and information contained within it, and (7) practice re-engineering. For detailed cost assumptions, please refer to Appendix 2: Intervention-Cost-Engine Estimates.

How Patient Participation Affects Value: ITDM Population-Selection Engine

The potential of diabetes management may be wasted if patients with diabetes are not actively identified, enrolled, engaged, and retained in such programs. We therefore modeled the effects of “churn”: the entry and subsequent withdrawal of patients from IT-enabled diabetes-management programs.

Data Sources

To assess rates for churn, we performed a targeted literature review and conducted interviews to estimate rates at which patients move through diabetes-management programs. To factor in the rates at which patients with diabetes would be eligible for participation in the first place, we extracted diabetes incidence and prevalence rates from the 2001–2002 National Health and Nutrition Examination Survey (NHANES) dataset. These incidence and prevalence rates were applied to all patients in the pool of patients, without regard to how frequently they are seen by a provider. Table 2–2 summarizes the various patient turnover rates used by the Population-Selection Engine.

Annual Rates Used by the Population-Selection Engine

Table
2-2

	Payer	Registry	CDSS	Remote Monitoring	Self-Management	Integrated
% of Patients Retained	95% ²⁹	93% ^{30, 31}	93% ^{30, 31}	93% ^{30, 31}	93% ^{30, 31}	93% ^{30, 31}
Diabetes Incidence	1.42%	1.42%	1.42%	1.42%	1.42%	1.42%
Diabetes Prevalence	11.5%	11.5%	11.5%	11.5%	11.5%	11.5%
% Successfully Identified for ITDM Program	93% ³²	93% ³²	93% ³²	91% ³³	91% ³³	93% ³²
% of Identified Patients Enrolled in ITDM Program	95% ^{16, 34}	100% [*]	100% [*]	18% ²¹	60% ³⁵	100% [*]
% of Enrolled Patients Retained in ITDM Program	98% ³⁶	100% [*]	100% [*]	98% ²¹	88% ³⁷	100% [*]

* Physician participation rate assumed to be 100%.

Model Development

Building and maintaining participation in diabetes-management programs involve several steps. Eligible patients must first be identified and invited to participate. However, enrollment into the program does not guarantee continued participation. Patients with diabetes may leave the program directly, or they may leave the provider panel or payer plan and no longer be eligible. This exit phenomenon is offset by new patients with diabetes entering provider panels and payer plans, and by non-diabetic member patients who may develop diabetes over time. We created the Population-Selection Engine to account for such factors. The Engine assumes that provider panels and payer plans remain at a constant size on average, and the number of annual new members is calculated accordingly.

How Costs and Benefits Apply to Different Settings: ITDM Net-Benefit Projection Engine

CITL created the Net-Benefit Projection Engine to apply the above engines to specific settings. The potential of ITDM to improve the health status of populations depends not only on the characteristics of the technologies but also on those of the population and care environments. For instance, populations with higher prevalence

rates of diabetes or with higher disease severity may have the potential to benefit more from ITDM. In any case, the model was designed to project the value of ITDM for any population, as defined by a set of key demographics and average health status of patients with diabetes.

Data Sources

Data from the U.S. Census and Centers for Medicare and Medicaid Services, among others, were used to create the distribution of payer panels.³⁸⁻⁴³ Data from the American Medical Association (AMA) and Community Tracking Study Physician Survey were used to create the distribution of provider practices. We derived national averages for diabetic-population characteristics from the 2000 Census and 2001-2002 NHANES.⁴⁴

Model Development

The Net-Benefit Projection Engine characterizes the distributions of providers and patients in organizations of various sizes. The Engine also describes the distribution of those organizations in order to aggregate the net benefit into a national figure. To be consistent with the CDC-RTI model, CITL eliminated all diabetes patients younger than age 25.

CITL split the national payer scenario into four arms: Medicaid Managed Care, Medicaid Fee-for-Service, Medicare Fee-for-Service, and a Payer Mix group that included both Medicare Managed Care and commercial insurers. To avoid double counting, individuals eligible both for Medicare and Medicaid were assigned to Medicare if they were age 65 or older and to Medicaid if they were younger than 65. Uninsured individuals and those covered by military health or consumer-directed health plans were excluded.

For provider-level analyses, CITL used AMA data to estimate the number of patients from the number of full-time specialist and primary-care providers who would treat diabetes.⁴⁵ We then applied age and gender adjustments⁴⁶ to account for part-time providers. To determine the distribution of diabetes-care providers by practice size, CITL used estimates of all primary-care physicians by practice size (extracted from the 2000-2001 Community Tracking Survey⁴⁷) and then scaled those estimates by the percentage of providers who treat patients with diabetes.⁴⁵

U.S. Census data were used to characterize the basic demographics of the general population as well as the population of each of the four insurance pools. On the basis of these demographics, which included age, gender, and ethnicity, the health status of an individual was projected. Health-status information included basic physiological parameters, such as systolic blood pressure, hemoglobin A1c, and cholesterol ratio, as well as prevalence of pre-existing co-morbidities such as heart attack, blindness, and stroke.

Sensitivity Analysis and Stability Testing

In CITL's ITDM Model, we defined specific disease states for patients with diabetes, such as having angina, and determined the probability of progressing to new disease states, such as having a cardiac arrest. Because it was impractical to analyze, one by one, all possible outcomes for all possible combinations of starting demographics and health statuses, the model was run as a Monte Carlo simulation. That is, a starting set of demographics and health statuses was randomly chosen, and the progressions for that simulated patient set was tracked and recorded. This process was repeated hundreds of thousands of times, in each run of the model, to estimate the outcomes for a particular population of patients. Because these simulation outcomes are not absolute, the model was run several times to test the stability of results. Such testing showed that the financial results varied by less than one percent between runs.

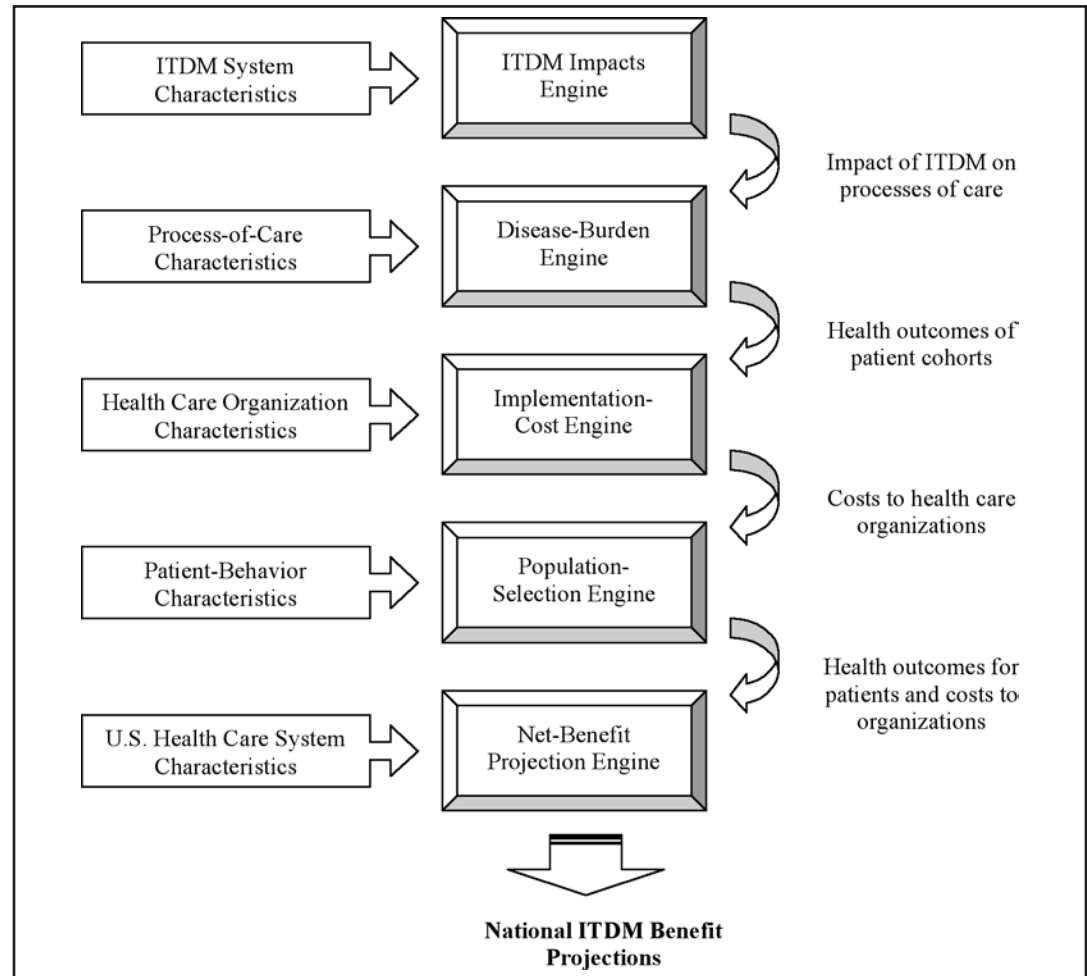
Key model inputs were also tested through a series of one-way sensitivity analyses. These variables included ITDM impact estimates used by the Intervention-Impacts Engine, patient-turnover rates used by the Population-Selection Engine, and discount rates used across the model. Model runs were conducted with values for key variables changed to reasonably high and low limits, as gleaned from our evidence collection process. Where no limits were discovered in the evidence, variables were increased and decreased by 25 percent.

Approach-to-Analysis Summary

The current literature does not include the long-term benefits of ITDM, and without such analysis it is difficult for organizations to make decisions on whether to invest and what kind of technology to invest in. CITL's five-engine model addresses these issues. The model was developed to allow for the input of various ITDM technologies, patient-population characteristics, features of health care organizations, and attributes of the U.S. health care system as a whole. The interaction of these inputs and model engines can be seen in Figure 2-3.

Figure
2-3

ITDM Model Overview



To fully appreciate the importance of each component of the CITL ITDM model, it is helpful to return to the questions and limitations listed earlier in the introduction to this report.

Do short-term changes using ITDM project out to long-term benefit?

The ITDM Impacts Engine applies best available evidence to the Disease-Burden Engine to show how process improvements can gradually alter the course of disease.

How do study results using ITDM generalize to other settings?

By applying specific demographic, epidemiologic, and organization data to the Disease-Burden Engine, Implementation-Cost Engine, and Net-Benefits Projection Engine, the value of ITDM can be estimated for different organizations and the nation.

What is the total cost of an ITDM system?

The Implementation-Cost Engine provides a comprehensive estimate of costs associated with implementation of ITDM, excluding certain costs as assumed (EMR, connectivity). Both cost of routine care and cost of diabetic complications are incorporated into the Disease-Burden Engine.

Are all eligible patients identified and enrolled in ITDM programs?

The Population-Selection Engine dilutes the potential value of ITDM by taking into account how successful programs are in identifying and enrolling diabetics into the program.

What happens to benefits when the patient changes ITDM programs?

The Population-Selection Engine accounts for patients with diabetes leaving and entering the program, and existing patients developing new-onset diabetes.

Does ITDM make sense for smaller organizations?

The Net-Benefits Projection Engine combines the estimated benefits with costs from the Implementation-Cost Engine to illustrate how economies of scale may operate with regard to ITDM.

Does ITDM make sense for the payers?

The Net-Benefits Projection Engine addresses the complete cost and benefit picture to show how ITDM may benefit payers as well as providers.

What are the ITDM technology options?

The ITDM taxonomy organizes the technology options into a framework that facilitates analysis, and the ITDM impact engine shows how various forms of ITDM may impact processes of care.

Common Assumptions

The model projected the value of each form of ITDM separately—combinations of two or more forms of ITDM were excluded from our analysis—and the results that follow reflect the impact of its full national adoption. We assumed that ITDM would be deployed uniformly over a five-year period, so that each year another 20 percent of all organizations would come on board. All diagnosed and insured patients with Type 2 diabetes older than age 25 were included in the analysis.

We assumed that the full impact of ITDM on process of care would be achieved in the first year of implementation, given that each of the contributing studies reported impact within 12 months. We also assumed that this impact remained constant over the ten years considered in this analysis, as long as a patient remained in the diabetes-management program. The costs of care for patients with diabetes were derived from the original CDC model and updated to reflect changes in standards of care. All financial values were calculated on a present-value basis, using a five percent discount rate.

Technologies Used by Payers

Payer interventions commonly include an integrated set of IT tools that enable targeted telephone-, Web-, and mail-based management of a diabetic population along with communication with these patients' providers. The main IT component of such diabetes-management programs is an in-house payer- or vendor-owned diabetes-registry software application. These systems interface with claims-based and select clinical data to update and integrate patient information. Diabetes-management programs may monitor diabetic outcomes, process measures, and values against accepted standards and recommended guidelines in order to provide feedback to patients and providers.

Patient Participation: Participation in payer programs would be relatively high. While some patients with diabetes might choose not to participate in diabetes management by payers, enrollment and retention rates would generally be far higher than in remote-monitoring and self-management programs.

Care Process: When fully implemented, national adoption of payer technologies would improve average:

- Retinopathy screening from 14 percent to 26 percent
- Peripheral neuropathy screening from 45 percent to 58 percent
- Microalbuminuria screening from 45 percent to 53 percent.

Physiology: When fully implemented, national adoption of payer technologies would improve average:

- Hemoglobin A1c (HbA1c) by 0.24 percent
- Systolic blood pressure (SBP) by 5.4 mmHg
- Cholesterol by 11 mg/dl.

Clinical Outcomes: Over the first ten years, national adoption of payer technologies would cumulatively reduce:

- Heart attacks by 54,000
- Strokes by 19,000
- Kidney failure by 3,000
- Amputations by 190,000
- Blindness by 18,000
- Diabetes-related mortality by 380,000.

Financial Outcomes: Over the first ten years, the national rollout of payer technologies would result in:

- Implementation cost of \$21.6 billion
- Cost-of-care savings of \$7.1 billion
- Overall net cost of \$14.5 billion.

Technologies Used by Providers

Diabetes Registries

Diabetes registries improve diabetic care in a number of ways. Through reminders at the point of care, registries can assist clinicians in making decisions that comply with diabetic guidelines. Through tools such as report cards, registries provide an opportunity for clinicians to identify potential for improvement across the panel of patients. Through mailed reminders to patients, registries can help heighten compliance and empower patients to be active participants in their own care.

Patient Participation: Participation in diabetes registries would be relatively high, as enrollment is typically automatic, and patients tend not to opt out. The primary source of patient non-participation would be failure by the management program to identify eligible candidates for enrollment.

Care Process: When fully implemented, national adoption of diabetes registries would improve average:

- Retinopathy screening from 14 percent to 62 percent
- Peripheral neuropathy screening from 45 percent to 80 percent
- Microalbuminuria screening from 45 percent to 66 percent.

Physiology: When fully implemented, national adoption of diabetes registries would improve average:

- HbA1c by 0.50 percent
- SBP by 1.1 mmHg
- Total cholesterol by 31 mg/dl.

Clinical Outcomes: Over the first ten years, national adoption of diabetes registries would cumulatively reduce:

- Heart attacks by 100,000
- Strokes by 5,200
- Kidney failure by 5,600
- Amputations by 560,000
- Blindness by 63,000
- Diabetes-related mortality by 710,000.

Financial Outcomes: Over the first ten years, the national rollout of diabetes registries would result in:

- Implementation cost of \$6.16 billion
- Cost-of-care savings of \$14.5 billion
- Net cost savings of \$8.34 billion.

Clinical Decision-Support Systems

Clinical decision-support systems are a powerful aid to clinicians at the point of care. By combining patient information with the latest medical knowledge, they offer recommendations to clinicians for optimal individualized care. Physicians can use these recommendations to improve control of blood sugars and other physiologic parameters as well as to improve compliance with screening and other care-process guidelines.

Patient Participation: Participation in CDSS would be relatively high, as patients generally do not choose to opt out. The primary source of patient non-participation would be failure by the management program to identify eligible candidates for enrollment.

Care Process: When fully implemented, national adoption of CDSS would improve average:

- Retinopathy screening from 14 percent to 24 percent
- Peripheral neuropathy screening from 45 percent to 68 percent
- Microalbuminuria screening from 45 percent to 61 percent.

Physiology: When fully implemented, national adoption of CDSS would improve average:

- HbA1c by 0.28 percent
- Increase in SBP by 4.0 mmHg.
- Total cholesterol by 4.5 mg/dl

Clinical Outcomes: Over the first ten years, national adoption of CDSS would cumulatively:

- Increase strokes by 12,000 (This result likely reflects the projected increase in blood pressure. See discussion section.)
- Reduce kidney failure by 2,600
- Reduce amputation by 340,000
- Reduce blindness by 20,000
- Reduce diabetes-related mortality by 210,000.

It would have no statistically significant effect on heart attacks (at $\alpha=0.05$).

Financial Outcomes: Over the first ten years, the national rollout of clinical decision support would result in:

- Implementation costs of \$19.3 billion
- Cost-of-care savings of \$10.7 billion
- Overall net cost of \$8.6 billion.

Technologies Used by Patients

Remote Monitoring

Remote-monitoring technologies allow clinicians to gauge the degree of control of a patient's diabetes between visits and to modify care plans accordingly. These technologies offer the potential to improve blood glucose, blood pressure, and cholesterol, for example.

Patient Participation: Participation in remote monitoring would be low. Many patients would choose not to enroll or to drop out after enrollment.

Care Process: When fully implemented, national adoption of remote monitoring technologies would have no statistically significant impact on provider decisions to screen for retinopathy, neuropathy, or microalbuminuria.

Physiology: When fully implemented, national adoption of remote-monitoring technologies would improve average:

- HbA1c by 0.03 percent
- SBP by 0.56 mmHg
- Total cholesterol by 2.8 mg/dl.

Clinical Outcomes: Over the first ten years, national adoption of remote-monitoring technologies would cumulatively reduce:

- Heart attacks by 12,000
- Diabetes-related mortality by 270,000.

It would have no statistically significant effect on strokes, kidney failure, amputations, or blindness (at $\alpha=0.05$).

Financial Outcomes: Over the first ten years, the national rollout of remote-monitoring technologies would result in:

- Implementation costs of \$6.83 billion
- Cost-of-care savings of \$326 million
- Overall net cost of \$6.5 billion.

Self-management

Self-management technologies provide patients with the information and tools that allow them to become active participants in their own care. Thus enabled, they can make healthy choices that improve control of blood sugar, blood pressure, and cholesterol; and they can have more informed discussions with their clinicians. However, because self-management technologies only have an indirect effect on a clinician's behavior, their influence on processes-of-care choices may be modest.

Patient Participation: Participation in self-management would be low. Many patients would choose not to enroll or to drop out after enrollment.

Care Process: When fully implemented, national adoption of self-management technologies would have no statistically significant impact on provider decisions to screen for retinopathy, neuropathy, or microalbuminuria.

Physiology: When fully implemented, national adoption of self-management technologies would improve average:

- HbA1c by 0.020 percent
- Total cholesterol by 7.9 mg/dl.

It would have no impact on SBP.

Clinical Outcomes: Over the first ten years, national adoption of self-management technologies would cumulatively reduce:

- Heart attacks by 26,000
- Diabetes-related mortality by 170,000.

It would have no statistically significant effect on strokes, kidney failure, amputations, or blindness (at $\alpha=0.05$).

Financial Outcomes: Over the first ten years, the national rollout of self-management technologies would result in:

- Implementation costs of \$16.2 billion
- Cost-of-care savings of \$285 million
- Overall net cost of \$15.9 billion.

Integrated Provider-Patient Systems

Integrated provider-patient systems would most fully achieve the envisioned benefits of diabetes management. They would help coordinate the efforts of all health care team members in delivering the best care possible, and they would provide patients with the tools to empower them in the management of their own health and to communicate effectively with their provider team (Table 3-1).

Patient Participation: We assumed that participation in integrated provider-patient systems would be high. The primary reason for non-participation would be the failure to identify eligible candidates.

Care Process: When fully implemented, national adoption of provider-patient systems would improve average:

- Retinopathy screening from 14 percent to 62 percent
- Peripheral neuropathy screening from 45 percent to 80 percent
- Microalbuminuria screening from 45 percent to 66 percent.

Physiology: When fully implemented, national adoption of provider-patient systems would improve average:

- HbA1c by 0.68 percent
- SBP by 4.2 mmHg
- Total cholesterol by 45 mg/dl.

Clinical Outcomes: Over the first ten years, national adoption of provider-patient systems would cumulatively reduce:

- Heart attacks by 160,000
- Strokes by 16,000
- Kidney failure by 7,900
- Amputations by 560,000
- Blindness by 64,000
- Diabetes-related mortality by 920,000.

Financial Outcomes: Over the first ten years, the national rollout of provider-patient technologies would result in:

- Implementation costs of \$58.8 billion
- Cost-of-care savings of \$16.9 billion
- Overall net cost of \$41.9 billion.

Table
3-1

Overview of 10-year Results

		Payer	Provider		Patient		Integrated System
			Registries	CDSS	Remote Monitor	Self Manage	
Financial	Care-Cost Savings (\$millions)	\$7,100	\$14,500	\$10,700	\$326	\$285	\$16,900
	System Cost (\$millions)	\$21,600	\$6,160	\$19,300	\$6,830	\$16,200	\$58,800
Screening	Eye Exam (Baseline 14%)	25.60%	61.50%	23.50%	14.20%	14.20%	61.50%
	Foot Exam (Baseline 45%)	57.80%	80.00%	67.50%	44.90%	44.90%	80.00%
	Microalbuminuria (Baseline 45%)	52.60%	66.10%	61.40%	45.00%	45.00%	66.10%
Physiology	HbA1c (%)	-0.24	-0.5	-0.28	-0.03	-0.02	-0.68
	SBP (mmHg)	-5.4	-1.1	4	-0.56	0	-4.2
	Total Cholesterol (mg/dl)	-11	-31	n/s	-2.8	-7.9	-45
Morbidity	ESRD	3,000	5,600	2,600	n/s	n/s	7,900
	Amputation	190,000	560,000	340,000	n/s	n/s	560,000
	Blindness	18,000	63,000	20,000	n/s	n/s	64,000
	Cardiac Arrest & Heart Attack	54,000	100,000	-4,500	12,000	26,000	160,000
	Stroke	19,000	5,200	-12,000	n/s	n/s	16,000
Mortality	Absolute Improvement	380,000	710,000	210,000	270,000	170,000	920,000
	Relative Improvement	1.90%	3.40%	1.00%	1.30%	0.83%	4.40%

n/s denotes lack of statistical significance at $\alpha=0.05$.

Mortality and morbidity results presented as reduction in ten-year cumulative incidence.

Net Benefit to Organizations

Because some forms of ITDM may achieve economies of scale, the overall net benefit picture may vary across organizations of different sizes. Across all organizational sizes for payer technologies, remote monitoring and self-management, ITDM costs more than it saves. Registries save more than they cost for all organizational sizes except single physician practices, and CDSS saves more than it costs for practices with greater than seven physicians (Table 3-2).

Net Benefit by Organizational Size for Registries and CDSS

Table
3-2

	CDSS	Registries
1 MD	-\$346,000	-\$17,000
2 MD	-\$293,000	\$46,000
3 MD	-\$231,000	\$120,000
4 MD	-\$154,000	\$211,000
5-6 MD	-\$69,000	\$312,000
7-9 MD	\$79,000	\$494,000
10-15 MD	\$347,000	\$816,000
16-25 MD	\$938,000	\$1,530,000
26-49 MD	\$1,650,000	\$2,360,000
50-75 MD	\$3,040,000	\$4,080,000
76-99 MD	\$4,220,000	\$5,580,000
100+ MD	\$17,000,000	\$21,400,000

Sensitivity Analysis and Stability Testing

One-way sensitivity analysis was performed against key variables: ITDM impact used by the ITDM Impacts Engine, patient-turnover rates used by the Population-Selection Engine, and discount rates used throughout the model. Across the range of ITDM impacts found in the literature, overall cost of care varied by up to 2.7 percent. Assuming a neutral effect on SBP by CDSS, cardiac complication rates improved by 2.1 percent, stroke rates improved by 0.56 percent, and an additional \$1.2 billion cost-of-care savings was generated, for a total of \$12 billion. Across a range of patient-turnover rates derived from the literature, cost of care varied by less than 4.0 percent. The discount rate was varied from 3.0 percent to 8.5 percent; cost of care increased by up to 14 percent and fell by up to 16 percent across this range.

Additional Benefits

The diabetes-management literature reports additional benefits that may add substantially to improved clinical and economic results projected by the model. For example, many programs incorporate smoking-cessation guidelines⁴ as part of their array of interventions.^{20,34,48,49} There is reason to believe not only that smoking cessation can improve health outcomes⁵⁰ but also that patients with diabetes probably benefit more than those without.⁵¹

Similarly, diabetic guidelines often include recommendations for other processes of care, such as vaccinations,^{4,52,53} exercise, nutrition therapy, and weight loss.⁴ Diabetes management may improve compliance with these recommendations,^{20,29,54,55} which in turn may improve the health of patients with diabetes.^{51,56,57}

However, it was not possible to incorporate these additional improvements into the model.

**ITDM Improves Care**

Our analysis demonstrates that all forms of ITDM improve processes of care, prevent development of diabetic complications, and generate cost-of-care savings. Technologies used by providers seem to be the most effective in improving the lives of patients with diabetes, and diabetes registries appear to be the most effective of all. Based upon the current evidence, our analysis indicates that patient-centered technologies offer the least potential for benefit. We believe that an integrated provider-patient platform, which adds patient-centered technologies to a registry and reminder system, would add benefits beyond a registry alone. This integrated platform would most fully achieve the envisioned benefits of diabetes management.

Cost Benefit Picture Varies by Technology

Not all forms of ITDM appear to be cost-beneficial. Diabetes registries are the only forms that are cost-beneficial in virtually all situations. CDSS is cost-beneficial only for larger provider organizations, and the remaining forms of ITDM are not cost-beneficial regardless of organizational size.

Cost Structure Varies Widely

The cost structures of the different technologies vary widely, and this has important implications on whether the associated programs can generate a net benefit. For example, remote monitoring and self-management technologies have large variable costs driven by the number of patients with diabetes who are managed. For self-management technologies, the cost of interventions such as intense health coaching is based on a per-intervened-patient-per-month (PIPM) model. Large components of remote monitoring costs include the costs of associated devices and subscription fees for each patient. These variable costs prevent economies of scale from being realized. This lack of economies of scale, together with the smaller benefit achieved by these technologies, prevent these programs from being cost-beneficial, even for large organizations in our model.

Payer technologies are also not cost beneficial for organizations of any size in our model, despite the presence of economies of scale. Larger payer organizations are often able to negotiate lower PIPM costs. However, cost reductions due to increased negotiating leverage still do not allow large payer groups to achieve a positive net benefit in our model.

Diabetes registries and CDSS achieve economies of scale because most costs are fixed, regardless of the number of patients managed. Benefits are highly dependant on the size

of the enterprise; each additional managed patient with diabetes brings the potential for added cost savings with little additional implementation cost. Thus these technologies become cost-beneficial for larger organizations.

Potential Benefit for Public Clinical Knowledge Repositories

The fixed costs associated with CDSS are the result of knowledge engineering tasks required to maintain clinical rules. Clinical rule sets must be created and maintained in order for EMRs to appropriately trigger alerts, reminders and other forms of decision support. If there were a publicly available national repository of relevant clinical knowledge, in such forms as alert and reminder logic, case finding definitions and report specifications, then a substantial cost would be lifted and the net benefit picture for CDSS might improve.

Market Inefficiencies May Foster Suboptimal Solutions

Because cost savings from improved care are largely reaped by payers, many diabetes-management programs are implemented by payers rather than providers. Furthermore, providers have been slow to adopt health information technologies that underpin diabetes management programs. Yet while implementation of payer technologies does improve the health of patients with diabetes and results in cost-of-care savings, providers are in the best position to improve care and control medical costs. This misalignment of incentives may be causing the market to pursue suboptimal interim solutions.

Key Limitations

These results reflect the synthesis of best available evidence, expert opinion, and a detailed simulation model predicting financial and clinical impact. Further, our sensitivity analyses have shown that the model is robust with respect to key variables. But although we believe these results to be the best estimate thus far of ITDM's costs and benefits, a few key limitations should be noted.

Strength of Evidence

Estimates of the impact of diabetes management are limited by the strength of the underlying evidence, with two sets of assumptions deserving particular attention. First, because the best available evidence regarding the effect of CDSS-based diabetes management on SBP showed a detrimental effect, our model projects worsening blood-pressure control with CDSSs. However, CDSSs in other settings show a neutral effect or improvement in blood-pressure control.^{58,59} Sensitivity analysis showed additional benefits, assuming a neutral effect on blood pressure; thus the model's results may underestimate the true value of CDSSs.

Second, the benefits of foot screenings may be overestimated. We were able to identify only one randomized controlled trial demonstrating the salutary effect of foot screening

on amputation rates.⁶⁰ Because the care assumed in this study may not reflect standards of care throughout the country, it may overestimate the benefits of foot screening.

Additionally, given the proprietary nature of cost information, it was difficult to obtain sufficient data to reflect the wide range of approaches currently found in diabetes management. Thus it was not possible to model the costs for all ways in which each type of technology is utilized in current practice. Based on interviews, extrapolation was required to project economies of scale and volume discounts. While we believe that all information shared in the interviews was accurate, the vendors could have under- or overestimated the costs of their program or product. Similarly, some of the practices, hospitals, and payers could have unintentionally omitted specific costs. Where possible, an unbiased third party reviewed the estimates.

Because of limited data, it was not possible to factor in the impact of organizational size in select cases. For example, estimates of CDSS costs in the model do not vary by organizational size. In reality, implementing an EMR modification in a large practice requires more time and planning to accommodate the requisite opinion leaders, while a smaller practice may implement a less customized set of guidelines to lower the cost. The impact of these size-specific considerations was not reflected in the model. Moreover, several other types of costs fall into this category. The cost of patient and provider recruitment/marketing, for example, was excluded because it varies widely by organizational size and particular program approach.

Population under Analysis

Generally, organizations target different subsets of patients for different interventions. For example, patients more severely affected by diabetes may receive interventions that are more intense and more expensive. Patients newly diagnosed with diabetes may receive more educational support. Organizations may adopt predictive modeling efforts to more precisely target interventions to those who would benefit the most. An analysis of such targeted approaches may change the net analysis. However, inclusion of severity stratification and predictive modeling was not possible for this report.

Scope of Benefits

The complications included in the model are important causes of patient suffering and account for a substantial portion of health care dollars attributable to diabetes. However, patients with diabetes consume health care resources that are not accounted for in our model, and savings from decreased utilization from other sources is not captured. For example, decreased admissions from influenza, pneumonia, uncontrolled hyperglycemia, and other general medical conditions may account for a substantial amount of savings. The American Diabetes Association (ADA) estimates that such complications account for \$44.1 billion, or roughly a third of total diabetic costs.³ Additionally, we did not model indirect costs—days lost from work, for example—though there is some evidence that such costs may be avoided through ITDM.⁶¹ The ADA estimates that indirect costs account for \$40.8 billion, again a third of total diabetic costs.

We assumed that diabetes prevalence rates would not increase and included only diagnosed patients in our analysis. However, prevalence rates are likely to increase in the future as diabetic risk factors such as obesity become more prevalent.^{62,63} Further, the ADA estimates that of the 20.8 million patients with diabetes in this country, more than six million remain undiagnosed.² Effective identification strategies within an overall disease-management program, with or without pre-diabetes components, might identify some of these undiagnosed patients. Whereas our model captures the incremental benefit of transitioning patients from existing levels of care to care under diabetes management, undiagnosed patients with diabetes represent potentially greater opportunities for improvement because they are currently untreated.

Finally, the infrastructure for diabetes management might be leveraged for the management of other chronic diseases, such as congestive heart failure or asthma. Where possible, such reuse might allow for additional benefits to be achieved without the full costs of starting a new disease management program from scratch.

Cross-Applicability of Studies

The evidence used in this analysis represents the best available data concerning the impacts of diabetes-management technologies on processes of care. However, applying estimates from one setting to projections in another can be hazardous. Diabetes-management programs show wide variation in a number of salient features, such as the programmatic elements included, the baseline quality of care, and the patient population. For instance, remote-monitoring technologies are often targeted toward severe or difficult-to-control populations, but extrapolating that experience to all patients with diabetes nationwide may introduce error.

Our analysis projects the impact of ITDM when offered to all patients with Type 2 diabetes in an organization or across the country. We include newly diagnosed or less severely affected patients with those at higher risk or who have already been affected by diabetic complications. Clearly, some of the newly diagnosed or less-severe patients may benefit from ITDM less than others. As a result, some organizations have adopted severity-stratification strategies or predictive modeling to target intervention to those patients with diabetes who may receive greatest benefit. This focusing of resources may yield a greater net benefit than is projected in our model.

Conclusion

While diabetes afflicts millions of Americans and can place a tremendous clinical and financial burden on our society, diabetes management offers an opportunity to improve care processes that enhance the lives of patients with diabetes and help control the medical costs associated with their disease. However, current diabetes-management strategies are limited by a lack of well-conducted studies for determining their specific impacts

on costs and benefits. Our own study suggests that ITDM would improve the lives of patients with diabetes and generate cost savings if widely adopted, but it also suggests that misaligned incentives may cause the market to underutilize provider-based forms of ITDM. Ironically, these may be the most cost-beneficial approaches of all.

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This research was funded through the Robert Wood Johnson Foundation, grant #049931. The Center for Information Technology Leadership (CITL), a research arm of Partners HealthCare, received unrestricted research support from the Health Information Management Systems Society over the time this research was conducted. Please refer to the CITL Web site (www.citl.org) for a full listing of past and current sponsors. None of the sponsors played a role in the design and conduct of the study; the collection, management, analysis, and interpretation of the data; or the preparation, review, and approval of the manuscript.

The authors acknowledge the members of our expert panel for their contributions. These expert panelists, excepting government employees, received nominal compensation for their time and efforts. The following individuals comprised the panel: Madhulika Agarwal, MD, MPH, Veterans Administration; Brian Austin, The Improving Chronic Illness Care Program, MacColl Institute for Healthcare Innovations, Group Health Cooperative; Stephen J. Brown, Health Hero Network; Lawrence P. Casalino, MD, PhD, University of Chicago; Timothy G. Ferris, MD, MPH, Partners/MGH Institute for Health Policy, Massachusetts General Hospital; Jeremy M. Grimshaw, MBChB, PhD, FRCGP, University of Ottawa; Karen M. Kuntz, ScD, Harvard School of Public Health; John A. Merenich, MD, Kaiser Permanente Colorado; and David Wennberg, MD, MPH, Health Dialog Data Services.

The authors would also like to acknowledge the Disease Management Association of America and Karen Fitzner, former Director of Research and Program Development, for their help; and Chris Colonian at CIGNA, Jaan Sidorov at Geisinger, and David Wright at American Healthways for their assistance with the payer information.

Additionally the authors would like to thank and acknowledge the following contributors: David Abelson, ParcNicollet; Michael Albisser, HumaLink; Doug Bach, Colorado Access; Bruce Barter, Centene Corporation; Susan Becker, Evanston Northwestern Healthcare; Heidi Bossley, AMA; Steve Brown, Health Hero; Wayne Burton, BankOne; Candy Chitty, Quality First Healthcare Consulting, Inc.; Jim Christian, PHCC LP; Nicole Cook, HCNetwork; Steve Delaronde, Connecticare; Gretchen Flanders, Colorado Access; Jonah Frohlich; Adam Habig and Teri Wallace, iSprit; John Haughom, PeaceHealth; John Haughton, DocSite; John Holland, LifeLink; Nancy Jarvis, ParcNicollet; Sharon Katz, Mills Peninsula Medical Group; Vince Kuraitis; Stan Lapidus, Rush University Medical Center; John Larsen, Cerner Corporation; Diane Lee, MEDai; Pat Lierman, Anthem; Kevin Maher, McKesson; David McCullough, GHC; Gretchen McGinnis; John Merenich, Kaiser; Lisa Mohr, BCBS of SC/Companion Health; Monica Neubauer,

Medica; Derek Newell, Lifemasters; Jeremy Nobel, Harvard School of Public Health; Gordon Norman, Pacificare; Dr. Gregory Preston, Keystone Mercy Health Plan; Doug Reagan, iMetrikus; Ed Rutherford, Tele minder; Chris Selecky, Lifemasters; Wells Shoemaker, PMG Santa Cruz; Skip Sievert, PHPMCS; Charlotte Silvers, Sid Peterson Memorial Hospital; Bob Stone, American Healthways; Mike Summers, McKesson; David Teitelman, Pacificare; Victor Villagra, Health and Technology Vector; Sandeep Wadhwa, McKesson; and Randy Williams, Pharos Innovations.

Appendix 1: Literature Summary | CITL



Summaries of the articles used in our ITDM Impacts Engine can be found below. The selection of articles was based on study design strength and closeness of fit to the taxonomy. The study findings presented below were either directly inputted into our model or served as the basis for calculated inputs. Preference was given to peer-reviewed literature.

Technologies Used by Payers

Newell and colleagues¹⁴ examined data of a LifeMasters program in a statewide health maintenance organization. The LifeMasters system compiled data from various sources (including remote-monitoring devices) and used algorithms to generate a customized intervention plan for staff to follow for each patient. One-page summaries for physicians displayed trends in blood pressure, weight, and blood-glucose data together with LifeMasters notes from patient interactions. Among patients with diabetes in the program for 12 months, average HbA1c decreased from 8.36 percent to 8.02 percent.⁶⁴

Data provided by the Geisinger Health Plan System's disease management program¹⁵ was analyzed and systolic blood pressure fell from 132.5 mmHg to 128.7 mmHg while LDL cholesterol levels fell from 114.0 mg/dl to 104.6 mg/dl.⁶⁵

Rubin and colleagues¹⁷ compared the experiences of patients with diabetes in seven HMOs at baseline and after 6–14 months in a program run by Diabetes Treatment Centers of America. The company's electronic tracking system included information about patient contacts, laboratory results, class attendance, hospital admissions, specialist visits, and ER use. Company staff worked both with patients and their physicians, sending reminders about screening and visits, supporting education, and providing nurse advocates. Screening rates for foot exams increased from 2 percent to 25 percent.

Villagra and Ahmed compared baseline and one-year intervention results in patients with diabetes enrolled in a disease-management program in 10 urban areas.¹⁶ A company software program included data from remote-monitoring devices and tracked patient progress. Patients had access to Web-based education and received phone calls from nurses as well as reminders and educational mailings. Annual dilated retinal exam rates increased from 40 percent in the baseline period to 48 percent in the follow-up period, and microalbuminuria screening rose from 27.3 percent to 37.3 percent.¹⁶

Diabetes Registries

Montori, et al.²⁰ reported that a diabetic electronic management system (DEMS) increased the frequency of microalbuminuria testing (27 percent to 55 percent), eye (36

percent to 69 percent) and foot (67 percent to 88 percent) exams and increased control of HbA1c levels, total cholesterol and blood pressure. The DEMS was used by all persons on the care team, and the system included workflow tools specific to each role. It issued care prompts based on guidelines from the ADA and it also allowed clinicians to set patient goals.

Clinical Decision-Support Systems

Meigs and colleagues¹⁸ conducted a one-year randomized controlled trial to evaluate a Web-based diabetes “disease-management application” with interactive decision support. After opening the application, clinicians saw a single-screen view of diabetes-related information about the patient, including trended and tabular laboratory results, reminders about routine exams, and specific treatment recommendations (e.g., “LDL exceeds goal of 100. Consider starting fluvastatin.”). The authors reported improved control of HbA1c levels, total cholesterol and blood pressure in the intervention group.

In a six-month randomized controlled trial, Lobach and Hammond¹⁹ compared use of a diabetes-specific encounter form to a standard encounter form. An algorithm first compared the local clinicians’ version of ADA guidelines to information in the patient’s EMR, and it then produced a paper form showing the guidelines, recommendations, and due dates for the patient. Median guideline compliance for the clinicians receiving the recommendations was 32.0 percent, compared to 15.6 percent in the control group and included higher rates of eye, foot and microalbuminuria screening.

Remote Monitoring

In a randomized controlled trial at the Veterans Affairs Boston Health Care System, McMahon, et al.²¹ monitored patients with diabetes at home through a Website that accepted uploads from a blood-pressure cuff and glucometer, offered access to educational modules and other Web-based diabetes resources, and facilitated online patient communication with a care manager. Based on glucose and hypertension treatment algorithms, the care manager provided recommendations to participants and primary-care providers. After 12 months, average HbA1c fell from 9.5 percent to 8.6 percent, SBP fell 10 mmHg from a baseline of 141 mmHg; and LDL cholesterol fell 6 mg/dl from a baseline of 100 mg/dl. Persistent users had better results.

Self-Management

In Glasgow and colleagues’ 10-month randomized trial,²² all patients had access to an Internet site with educational materials and a goal-setting dietary program. A subset of patients also had an online dietary coach they could access twice a week, and another subset participated in online discussions with other patients and received electronic newsletters.

Appendix 2: Intervention-Cost-Engine Estimates

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All estimates for the intervention-cost engine are broken down into two categories, acquisition and annual. Acquisition costs are allocated to Year 1, whereas annual costs are incurred on an ongoing basis.

Payer Mediated Intervention Acquisition and Annual Costs

Table
A-1

	Acquisition (Year 1 only)	Annual (Years 1-10)
Identification	2 weeks of IT staff time to set up and run claims analysis to identify patients with diabetes	IT staff time for monthly refreshes of claims analysis to identify patients with diabetes
Program Implementation Fee	One time fee: \$125,000	None
Support Staff	Program manager, IT staff, and physician time to support the implementation of intervention	Program manager, IT staff, and physician time to support intervention
Program Fee	None	Per-intervened-member-per-month fee varied by insurance type and organization size

Table
A-2

Registry with Reminders Acquisition and Annual Costs

	Acquisition (Year 1 only)	Annual (Years 1-10)
Identification	2 weeks of IT staff time to set up and run claims analysis to identify patients with diabetes	IT staff time for monthly refreshes of claims analysis to identify patients with diabetes
Hardware	Personal computer per physician: \$500	5 year hardware replacement
Software	None	Licensing fee for software and hosting services, includes IT support
Interfaces	3 interfaces: \$10,000 each	17.5% of acquisition costs
IT Support Staff	None	None
Training	Vendor expenses plus physician and program manager time for training	Annual new employee training costs at 20% of acquisition costs
Non-IT Programmatic Costs	None	Quarterly appointment reminder mailings: \$4 per-intervened-member-per-year fee

Table
A-3

Modified EMR with Clinical Decision Support Acquisition and Annual Costs

	Acquisition (Year 1 only)	Annual (Years 1-10)
Identification	None—patients with diabetes identified during clinical encounters by physicians	None
Hardware	None—EHR is preexisting technology	None
Software	200 hours of IT staff time to develop ED forms, flow sheets, referral forms, smart text and order sets, plus cost of standard reporting tool	20% of acquisition costs
Interfaces	None— interfaces already exist	None
IT Support Staff	10 hours of endocrinologist time to operationalize ADA guidelines	10 hours of endocrinologist time to update ADA guidelines
Training	None—training occurs during initial EHR implementation	None
Non-IT Programmatic Costs	None	None

Remote Monitoring Acquisition and Annual Costs

Table
A-4

	Acquisition (Year 1 only)	Annual (Years 1-10)
Identification	2 days of IT staff time to set up and run claims analysis to identify patients with diabetes	IT staff time for monthly refreshes of claims analysis to identify patients with diabetes
Hardware	Phone data transmission device for each patient: \$100-\$160; PC for each RN: \$500	5 year hardware replacement
Software	One time fee: \$500-\$1,500	Annual per patient fee (\$25-\$50) and per RN fee (\$70-\$90)
Interfaces	1 interface: \$10,000	17.5% of acquisition costs
IT Support Staff	None	None
Training	Cost of 1 web-ex training session (\$250) and 8 hrs of RN time; Fee per RN for IT support (\$12)	Fee per patient (\$12); 20% of staff training acquisition costs for new staff
Non-IT Programmatic Costs	None	Registered nurse time per 300 patients with diabetes

Self Management Acquisition and Annual Costs

Table
A-5

	Acquisition (Year 1 only)	Annual (Years 1-10)
Identification	2 days of IT staff time to set up and run claims analysis to identify patients with diabetes	IT staff time for monthly refreshes of claims analysis
Hardware	PC for each dietician: \$500	5 year hardware replacement
Software	One time fee: \$500	Annual per patient fee (\$70-\$90) and per dietician fee (\$70-\$90)
Interfaces	1 interface: \$10,000	17.5% of acquisition costs
IT Support Staff	None	None
Training	Cost of 1 web-ex training session (\$250-\$300) and 8 hrs of dietician time; Fee per dietician for IT support (\$12)	\$12 fee per patient; cost of web-ex training (\$250-\$300), hosting an average 150 patients; 20% of staff training acquisition costs for new staff
Non-IT Programmatic Costs	None	Dietician time per 300 patients with diabetes

Table
A-6

Integrated Platform Acquisition and Annual Costs

	Acquisition (Year 1 only)	Annual (Years 1-10)
Identification	2 weeks of IT staff time to set up and run claims analysis to identify patients with diabetes	IT staff time for monthly refreshes of claims analysis to identify patients with diabetes
Hardware	PC for each dietician, nurse, and provider: \$500 each; phone data transmission device for each patient: \$100-\$160 each, scaled by organization	5 year hardware replacement
Software	One time fee: \$500-\$1,500	RM: Annual per patient fee (\$25-\$50) and per RN fee (\$70-\$90)
		SM: Annual license fee per patient (\$70-\$90) and per dietician (\$70-\$90)
		Registry: Annual license and hosting fee for provider
Interfaces	3 interfaces: \$10,000 each	17.5% of acquisition costs
IT Support Staff	None	None
Training	RM: Cost of 1 web-ex training session (\$250) and 8 hrs of RN time; \$12 fee per RN for IT support	\$12 fee per patient; cost of web-ex training (\$250-\$300), hosting an average 150 patients for combined self management and remote monitoring training; 20% of registry training acquisition costs for new staff training
	SM: Cost of 1 web-ex training session (\$250-\$300) and 8 hrs of dietician time; Fee per dietician for IT support (\$12)	
	Registry: vendor expenses plus physician and program manager time for training	
Non-IT Programmatic Costs	None	SM: Dietician time per 300 patients with diabetes
		RM: Registered nurse time per 300 patients with diabetes
		Registry: Quarterly appointment reminder mailings: \$4 per-intervened-member-per-year fee

Appendix 3: Expert-Panel Biographies | CITL



Madhulika Agarwal, MD, MPH, Acting Deputy Chief Officer of Patient Care Services, Veterans Health Administration

Dr. Agarwal is an internist who currently serves as the Deputy Chief Officer of Patient Care Services in the Veterans Health Administration's Office of Patient Care Services. In this capacity, she is the principal advisor to the VHA's Undersecretary of Health on policy issues that relate to patient care and clinical services.

VHA provides health care to more than 5.1 million veterans and 7.6 million enrollees throughout the United States. With a medical-care budget of approximately \$30 billion, VHA directly employs more than 196,500 health care professionals at more than 1,300 sites of care, including hospitals, community- and facility-based clinics, nursing homes, domiciliaries, readjustment counseling centers, and various other facilities. In addition to its medical-care mission, VHA is the nation's largest provider of graduate medical education and a major contributor to medical and scientific research. More than 125,000 volunteers, 80,000 health profession trainees, and 25,000 affiliated medical faculty are an integral part of the VHA community.

Dr. Agarwal received her MD degree from Rajasthan University in India. She completed her training in internal medicine at the VA Medical Center–Georgetown University program in Washington, D.C. She is a Diplomate of the American Board of Internal Medicine. She has also completed her Masters in Public Health at George Washington University in Washington, D.C.

Dr. Agarwal previously served as the Associate Chief of Staff for Ambulatory Care at the VA Medical Center, Washington, D.C., where she oversaw primary care, emergency-room services, and the Community-Based Outpatient Clinics. She has also been involved in training medical students and residents as well as in health-services research. She holds a faculty appointment as Assistant Professor in the Department of Medicine at Georgetown University.

Brian Austin, Deputy Director, Improving Chronic Illness Care, and Associate Director, MacColl Institute for Health Care Innovation, Seattle

Mr. Austin is Deputy Director of Improving Chronic Illness Care (ICIC), a national program of the Robert Wood Johnson Foundation; and Associate Director of the Group Health Cooperative's MacColl Institute for Health Care Innovation, which he helped found in 1992. The MacColl Institute is devoted to developing and disseminating innovations in the delivery of health care, especially within a primary-care environment.

Mr. Austin is also a co-developer of the Chronic Care Model, a systems approach for improving the delivery of care to the chronically ill, which MacColl has been testing and refining since the mid-1990s. The Model has been widely published and broadly adopted as an organizing framework, both nationally and internationally. Since 1998, the MacColl Institute has also served as the home for ICIC, for which Mr. Austin has been the lead administrator since its inception. He is also a member of the administrative leadership team of the Group Health Cooperative's Center for Health Studies (the Group Health Cooperative is the MacColl Institute's parent). The Center conducts epidemiologic, health-services, behavioral, and clinical research addressing a wide and evolving range of clinical and public health questions.

Stephen J. Brown, President and CEO, Health Hero Network, Redwood City, Calif.

Mr. Brown is the founder of the Health Hero Network. During his leadership as CEO, the company has secured over \$50 million in private financing to develop and commercialize the Health Buddy[®] system, a technology platform that educates and monitors patients at home and links them to chronic-care improvement services. The Health Hero Network is recognized as an industry-leading innovator and solution-provider in care management, with demonstrated and published outcomes showing quality improvement and cost-effectiveness for major health care institutions. Mr. Brown began his career by developing disease-management systems and software for pharmaceutical and medical-device companies while conducting research on interactive technologies for improving patient self-care and health-related behavior. Mr. Brown's research has included some of the first interactive television and information-appliance applications for disease management, patient education, and behavioral health, resulting in over 50 patents assigned to Health Hero Network. Mr. Brown graduated with a BS in Physics from Stanford University.

Lawrence P. Casalino, MD, PhD, Assistant Professor, University of Chicago

Dr. Casalino is a physician and health-services researcher at the University of Chicago. In addition to his 20 years as a family physician in private practice, he earned a PhD in health-services research, with a focus on organizational and institutional sociology and economics. He is a recipient of an Investigator Award in Health Policy Research from the Robert Wood Johnson Foundation. Dr. Casalino conducts research in two main areas: the effects of varying forms of organization on physician practice and the effects of physician/hospital and physician/health-plan relationships on the quality and costs of medical care. He also studies the ways in which public and private policies shape these forms and relationships. Among the journals in which his work has been published are the *New England Journal of Medicine*, the *Journal of the American Medical Association*, *Health Affairs*, *Health Services Research*, the *Journal of Health and Social Behavior*, and the *Journal of Health Politics, Policy and Law*.

Timothy G. Ferris, MD, MPH, Partners/MGH Institute for Health Policy, Massachusetts General Hospital, Boston

Dr. Ferris is a practicing general internist and pediatrician, Vice Chair for Quality and Safety for Partners Pediatrics, and a senior scientist in the Partners/MGH Institute for Health Policy. He directs disease-management programs at Partners HealthCare, with specific responsibility for design, oversight, and evaluation of programs to improve quality and efficiency of care for high-risk patients such as those with heart failure. His research has focused on quality-improvement interventions for adults' and children's health care. In addition, he has studied the effects of the organization and financing on the costs and quality of care, risk adjustment of quality measures, and disparities in health care. Dr. Ferris has been a member of the Health Care Quality and Effectiveness Research study section of the Agency for Healthcare Research and Quality, and he has chaired two Technical Advisory Panels for the National Quality Forum.

Jeremy Grimshaw, MBChB, Director, Centre for Best Practices, Institute of Population Health, University of Ottawa

Jeremy Grimshaw received an MBChB (MD equivalent) from the University of Edinburgh, U.K. He trained as a family physician prior to earning a PhD in health services research at the University of Aberdeen. He moved to Canada in 2002. His research focuses on the evaluation of interventions to disseminate and implement evidence-based practice. Dr. Grimshaw is Director of the Clinical Epidemiology Program at the Ottawa Health Research Institute; Director of the Centre for Best Practices at the University of Ottawa's Institute of Population Health; Director of the Canadian Cochrane Network and Centre; and Tier 1 Canada Research Chair in Health Knowledge Transfer and Uptake. He is a full professor in the Department of Medicine, University of Ottawa, with a cross-appointment to the Faculty of Medicine's Department of Epidemiology and Community Medicine.

Earlier, Dr. Grimshaw held a Personal Chair in Health Services Research at the University of Aberdeen, U.K. and was the Program Director of the Effective Professional Program within the Health Services Research—probably the largest research-implementation program in the U.K. Dr. Grimshaw has established a comparable program in Ottawa. He has a full registration with the General Medical Council and is member and Fellow of the Royal College of General Practitioners.

Dr. Grimshaw's research interests can be grouped according to three themes: systematic reviews of professional, organizational, financial, and regulatory interventions to improve professional and health care system performance; the design, conduct, and analysis of rigorous evaluations of dissemination and implementation strategies; and guideline-development methods.

Karen M. Kuntz, ScD, Associate Professor, Harvard School of Public Health, Boston

Dr. Kuntz is Associate Professor of Decision Science in the Department of Health Policy and Management at the Harvard School of Public Health. She is an internationally recognized decision analyst with extensive experience in the methods and applications of simulation modeling for evaluating clinical and public health strategies. She is currently principal investigator of one of the NCI-funded Cancer Intervention and Surveillance Modeling Network (CISNET) grants to evaluate national trends in colorectal cancer incidence and mortality. Dr. Kuntz has become one of the leading authorities on describing errors and biases that can occur in disease modeling. She received her masters and doctorate, both in biostatistics, from the Harvard School of Public Health.

John A. Merenich, MD, Regional Director of the Colorado Permanente Care Management Institute (Chronic Disease Management Program), Colorado Permanente Medical Group, Denver

Dr. Merenich is a practicing physician and Regional Director of the Colorado Permanente Care Management Institute (CMI) for Kaiser Permanente, a major health care provider in Colorado. He supports CMI's stated vision to "synthesize knowledge about the best clinical approaches and create, implement, and evaluate effective and efficient health care programs to improve the health of our members and community." Or, stated more simply: "To make the right thing easier to do."

Prior to joining Kaiser Permanente Medical Group, Dr. Merenich completed 10 years of active duty with the U.S. Army. While at Fitzsimons Army Medical Center, he completed a fellowship and served as a research fellow in endocrinology and metabolism. Along with his current responsibilities at CMI, he is an Associate Professor of Medicine at the University of Colorado Health Science Center in Denver.

Dr. Merenich's undergraduate training was in biology and he received his MD from Hahnemann University and Hospital, Philadelphia. He has published many articles and book chapters on topics that include evaluation of the role of drug therapy, cardiac risk, and lipid management in endocrine disorders. He is the recipient of several awards in recognition of his excellence in providing superior patient care.

David Wennberg, MD, MPH, President and COO, Health Dialog Analytic Solutions, Boston

Dr. Wennberg is President and Chief Operating Officer of Health Dialog Analytic Solutions and Director of the Center for Outcomes Research and Evaluation, Maine Medical Center. He graduated from the McGill University Faculty of Medicine in 1987. Dr. Wennberg's post-graduate education was in internal medicine at the Maine Medical Center. Following his residency, he was a fellow in general internal medicine at the Harvard Combined Program and received an MPH from the Harvard School of Public

Health. An internist with specialty training in health services and outcomes research, his major research interest is quality of care for cardiovascular services. Dr. Wennberg has worked with Health Dialog for six years, directing the company's segmentation and analytic services for the Collaborative CareSM product line. In addition to helping found and run Health Dialog Analytic Solutions, he leads a nationally recognized research team at the Maine Medical Center, focusing on the drivers of utilization and quality in the delivery of health care services.

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*This index is designed to help the user easily locate topics of interest. When the letter “f” follows a page number, it indicates that the term is located in a figure; the “t” indicates that the term is located in a table.

A

American Diabetes Association (ADA), 1, 35
 American Medical Association (AMA), 18
 Application service provider (ASP) model, 14
 Automated phone systems, 9

B

Biographies

Agarwal, Madhulika, 7, 47
 Austin, Brian, 7, 47–48
 Brown, Stephen J., 7, 48
 Casalino, Lawrence P., 7, 48
 Ferris, Timothy G., 8, 49
 Grimshaw, Jeremy, 8, 49
 Kuntz, Karen M., 8, 50
 Merenich, John A., 8, 50
 Wennberg, David, 8, 50–51

Blindness, 1

Blood-sugar monitoring, 1

C

CDC/RTI Diabetes Cost-Effectiveness
 model, 12

Center for Information Technology
 Leadership (CITL), 5

Centers for Disease Control and Prevention
 (CDC), 12

Chronic care model, 1–2, 2f

Clinical decision-support systems (CDSSs),
 9, 14–15, 26, 42
 care process, 26
 clinical outcomes, 26
 economies of scale for, 33–34
 financial outcomes, 26
 fixed costs associated with, 34
 net benefit by organizational size for, 31t
 patient participation, 26
 physiology, 26

Clinical rule, 34

Commercial insurers, 18

Community Tracking Study Physician
 Survey, 18

Complications, reduction in, 7f

Coronary heart disease (CHD),
 complications of, 12

Cost benefit, 33

Cost modeling, assumptions in, 15–16

Cost structure, 33

Cross-applicability of studies, 36

D

Data, 10, 11t, 12

Death, 1

Demographic shifts, 1

Diabetes

complications of, 1, 12

defined, 1

indirect costs of, 1

number of patients with, 1

outlook for patients with, 1

Diabetes-management programs,
 effectiveness of, 4

Diabetes registries, 25, 33, 41–42

care process, 25

clinical outcomes, 25

economies of scale for, 33–34

financial outcomes, 25

net benefit by organizational size for,
 31t

participation in, 25

patient participation, 25

physiology, 25

with reminders acquisition and annual
 costs, 44t

Diabetes Treatment Centers of America, 41

- Diabetic electronic management system (DEMS), 41–42
- Diabetic guidelines, 32
 - compliance with, 1
- Dietary recommendation, 1
- Disease management
 - components of, 3*f*
 - defined, 2
- Disease Management Association of America (DMAA), 13
- Disease registry, 10

E

- Electronic-claims systems, 8
- Electronic diary tools, 9
- Electronic medical records (EMRs), 9
- Exercise, 1

F

- Foot inspection, 1
- Foot screenings, benefits of, 34–35

G

- Geisinger Health Plan System's disease management program, 41

H

- Health Care Delivery Work Group, 2
- Health-status information, 18
- Heart disease, 1
- Hemoglobin A1c (HbA1c) levels, 9

I

- Implementation fee, 14
- Information technology (IT), advantages of, 2–3
- Information technology (IT)-enabled
 - diabetes management (ITDM), 3–5, 7
 - Disease-Burden Engine, 11–12, 13*f*
 - Impacts Engine, 10–11, 11*t*
 - Implementation-Cost Engine, 13–16
 - improvement of care and, 33
 - Net-Benefit Project Engine, 17–18
 - Population-Selection Engine, 16–17, 17*t*
 - for small provider organizations, 4

- Information technology (IT)-enabled
 - diabetes management (ITDM)
 - taxonomy, 8–10

- Insulin, 1

- Integrated platform acquisition and annual costs, 46*t*

- Integrated provider-patient systems, 10, 15, 29, 30*t*
 - care process, 29
 - clinical outcomes, 29
 - financial outcomes, 29
 - patient participation, 29
 - physiology, 29

- Interactive educational programs, 9

- Intervention-Cost-Engine estimates, 43*t*

- integrated platform acquisition and annual costs, 46*t*

- modified EHR with clinical decision support acquisition and annual costs, 44*t*

- payer mediated intervention acquisition and annual costs, 43*t*

- registry with reminders acquisition and annual costs, 44*t*

- remote monitoring acquisition and annual costs, 45*t*

- self management acquisition and annual costs, 45*t*

L

- Landmark studies, 1

- Laser eye surgery, 1

- LifeMasters system, 41

- Literature summary, 41–42

- Long-term benefit, 3–4

M

- Market inefficiencies, 34

- Medicaid Fee-for-Service, 18

- Medicaid Managed Care, 18

- Medicare Fee-for-Service, 18

- Medicare Managed Care, 18

- Models, 11, 12, 13*f*

- Modified EHR with clinical decision support acquisition and annual costs, 44*t*

- Monte Carlo simulations, 19

- Multidisciplinary care, 1–2

N

National Health and Nutrition Examination Survey (NHANES), 16
National Institutes of Health's Behavioral Research and Diabetes Conference, 2
Nephropathy, complications of, 12
Net-Benefit Projection Engine, 18
Net benefit to organizations, 31

O

One-way sensitivity analyses, 19
Online resources, 9

P

Patient education tools, 10
Patients
 effect of participation on value, 16
 technologies used by, 9–10, 15, 27–28
Payer interventions, 23
 care process, 24
 clinical outcomes, 24
 financial outcomes, 24
 patient participation, 23
 physiology, 24
Payer mediated intervention acquisition and annual costs, 43*t*
Payer Mix group, 18
Payers, technologies used by, 8–9, 14, 23–24, 41
Payer systems, 8–9
Payer technologies, 33
Peer support groups, 9
Per-intervened-patient-per-month (PIPM) model, 14, 33
Peripheral neuropathy, complications of, 12
Processes of care
 changes in, 11–12, 13*f*
 technologies effect on, 10–11, 11*t*
Providers, technologies used by, 9, 14–15, 25–26
Public clinical knowledge repositories, 34

R

Remote-monitoring, 27–28, 42
 acquisition and annual costs, 45*t*
 care process, 27

 clinical outcomes, 27
 financial outcomes, 27
 patient participation, 27
 physiology, 27
Remote-monitoring devices, 10
Remote-monitoring technologies, 9–10
Research Triangle Institute (RTI), 12
Retinopathy, complications of, 12

S

Self-management, 9, 10, 15, 27, 42
 acquisition and annual costs, 45*t*
 care process, 27
 clinical outcomes, 27
 financial outcomes, 27
 patient participation, 27
 physiology, 27
Sensitivity analysis, 19, 32, 34
Short-term improvements, 3–4
Smoking-cessation guidelines, 32
Stability testing, 19, 32
Strokes, 1

T

Technologies
 effect on processes of care, 10–11, 11*t*
 used by patients, 9–10, 15, 27–28
 used by payers, 8–9, 14, 23–24, 41
 used by providers, 9, 14–15, 25–26

U

United Kingdom Prospective Diabetes Study, 12

V

Value, effect of patient participation on, 16
Veterans Affairs Boston Health Care System, 42

W

Web site, 9–10

